

**REMARKS**

Claims 2-6, 8-15, 25-30 and 32 currently appear in this application. The Office Action of November 1, 2006, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicant respectfully requests favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

**Specification**

The amendment filed May 17, 2006, is objected to because the Examiner alleges that the added material is not supported by the original disclosure, namely, introducing the term -without- in place of "with" on page 9, line 6.

It is respectfully submitted that the amendment filed May 17, 2006, did not contain new matter, as it is clear that the Z value compare an average for patients without bone metastasis with the standard deviation of a patient without bone metastasis. The narrative on page 8, beginning at line 6, describes testing the progress of patients with prostatic cancer without bone metastasis.

Claim Objections

Claim 8 is objected to because the term "osteoblastor" on line 4 should be replaced by -osteoblasts or--. The present amendment effects this change.

Rejections under 35 U.S.C. 112

Claims 2-6, 8-15, 25-30 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description. The Examiner alleges that amending claims 6, 8 and 30 to recite "an average value without bone metastasis" is new matter.

This rejection is respectfully traversed. For the reason given above. It is clear that the patients evaluated were those without bone metastasis, and that the Z value was a comparison of the measured value for the patient and an average value for patients without bone metastasis by a standard deviation of a patient without bone metastasis. Otherwise, the Z value does not make sense, as one would not compare patients with bone metastasis to patients without bone metastasis.

Claims 2-6, 8-15, 25-30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that applicants are requested to clarify how the

crossover index score defines or aids in determining whether or not there is amelioration and/or exacerbation of metastasis and the efficacy of drugs for cancer treatment.

This rejection is respectfully traversed. Use of the crossover index is explained in detail in the specification as filed beginning on page 8, line 6. The crossover index demonstrates diagnosis of the progression of bone metastasis for breast or prostate or other cancer, and, by measuring the patient's response to drug therapy, makes it possible to evaluate if the drug therapy is helping the patient. Claim 8 has been amended to recite that a lower crossover index indicates amelioration of the patient's condition. Support for this amendment can be found in the specification as filed at page 9, lines 20-38.

Claim 8 is rejected as being vague and indefinite because the claim notes in the preamble that the evaluation of the efficacy of drugs is based on assessing one marker of osteoblast activity or one marker of osteoclast activity.

This rejection is respectfully traversed. Claim 8 has been amended to recite "at least one of."

Claim 32 is rejected as being indefinite because the method steps are said to read on measuring a marker for bone formation and a marker for bone resorption.

This rejection is respectfully traversed. Claim 32 recites that the marker for bone resorption comprises ICTP. Claim 32 also recites testing for a marker for bone formation, but does not recite a specific marker, meaning that any marker for bone formation can be used.

Claim 32 is rejected as being indefinite because of lack of antecedent basis for "the measured values", for "the improvement" and for "expressing the measured values in terms of standard error."

This rejection is respectfully traversed. Claim 32 has been amended to correct the lack of antecedent basis and the indefinite language. Claim 32 is a Jepson-type claim, and is written "In a method for..." and contains the phrase "the improvement wherein", which means that in a method for evaluating the efficacy of a drug for treatment of cancer or inhibition or amelioration of a metastasis of said cancer to bone in a patient with cancer, the improvement comprises testing the serum of the patient for a marker of bone formation, testing said serum for a marker of bone resorption, expressing measured values in terms of average and standard error, analyzing variants according to the Bonferroni method, and noting that the progression of disease is denoted by ICTP values.

Average and standard error are defined in the specification at page 9, lines 5-8, namely, the average for patients without bone metastasis and the standard deviation of a patient without bone metastasis.

Prior Art

It is noted that the prior art made of record and not relied upon is merely considered to be pertinent to applicant's disclosure.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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